

**DEPARTMENT OF AGRICULTURE****Food Safety and Inspection Service**

[Docket No. FSIS-2018-0041]

Availability of Kit Product Labeling Guideline

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and response to comments.

SUMMARY: In July 2019, the Food Safety and Inspection Service (FSIS) published and requested comment on a guideline for establishments producing multi-component kit products that contain inspected and assembled meat or poultry components. FSIS is announcing updates to this guideline and responding to comments received on the guideline. FSIS intends for this guideline to help establishments and other food handling facilities producing a multi-component food kit determine whether the kit product needs to be prepared under FSIS inspection and how to label a kit product that contains fully labeled meat or poultry components. The guideline represents current FSIS thinking, and FSIS will update it as necessary to reflect comments received and any additional information that becomes available.

ADDRESSES: A downloadable version of the kit guideline is available to view and print at:

<https://www.fsis.usda.gov/policy/fsis-guidelines>. No hard copies of the kit guideline have been published.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant

Administrator, Office of Policy and Program Development by telephone at (202) 205-0425.

SUPPLEMENTARY INFORMATION:

Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.) to, in part, ensure that the labeling of meat, poultry and egg products is truthful and not misleading. Mandatory labeling requirements for meat and poultry products are prescribed in Title 9 of the Code of Federal Regulations (CFR) section 317.2 and part 381 subpart N.

On July 9, 2019, FSIS announced the availability of and requested comment on the *Food Safety and Inspection Service Guideline on Kit Labeling* (84 FR 32705). FSIS developed the guideline for establishments and other food handling facilities to provide information on the labeling and inspection of multi-component food kit products that contain an inspected and assembled meat or poultry component.

There are many varieties of food kit products that contain meat or poultry products, including, but not limited to: wraps, pizza, stew, salads, fajitas, stroganoff, and stir-fry skillet meals. These items are commonly sold as fully cooked, but some may require cooking. Generally, the meat and poultry components are separately wrapped and already inspected and fully labeled

before assembly with various food components in the same packaging.

As announced in the July 2019 guideline, FSIS determined that the act of assembling a food kit product whose label refers to meat or poultry in its name does not need to be done under FSIS inspection, provided that the meat or poultry component has already be inspected, packaged, and labeled and as long as the following conditions are met:

1. The meat or poultry component is prepared and separately packaged under FSIS inspection and labeled with all required features, including:
 - Product Name;
 - Handling statement (e.g., Keep Refrigerated), if product is perishable;
 - USDA legend and establishment number of the official establishment that packaged and labeled the meat or poultry component;
 - Name and address of the manufacturer, packer, or distributor;
 - Ingredients statement (if composed of more than one ingredient); and
 - Safe handling instructions if the meat or poultry components is not ready-to-eat;
2. The outer kit label clearly identifies all the individual components in the kit; and

3. The outer kit label clearly identifies the product as a single unit or "kit" such as "Chicken Barbecue Dinner Kit" and "Beef Lasagna Meal."

Although FSIS will no longer conduct mandatory inspection of the assembly of the kit product, the meat or poultry component of the kit remains under FSIS' jurisdiction and, as such, is required to meet all applicable FSIS labeling requirements.

The revised guideline is posted at:

<https://www.fsis.usda.gov/policy/fsis-guidelines>. Although

comments will no longer be accepted through

<https://www.regulations.gov/> on this guideline, FSIS will update this document as necessary if new information becomes available.

Comments and FSIS Responses

FSIS received 15 comments on the kit guideline. Most comments were submitted by firms that prepare kits and trade associations that represent the meat and retail industries. In addition, FSIS received comments from an animal welfare organization, a firm that exports kit products from the United States, an FSIS employee, and several individuals. The following is a summary of the comments and FSIS' responses:

Kit Definition

Comment: One consumer requested that FSIS provide a clearer definition of a kit and clarify whether Agency policy distinguishes between a kit and a meal kit. One firm that prepares kits similarly requested a clearer definition of a kit

and asked for additional guidance on the distinction between a single unit and a kit.

Response: As stated in the guideline, a kit product consists of individually packaged meat or poultry components and other food components sold together as a single unit. FSIS policy does not distinguish between the terms "kit", "meal kit", or "single unit." Although the word "kit" is not required on the label, all labeling should clearly indicate that the product consists of individual components. Because this information is already stated in the guideline, FSIS did not make any changes to it in response to these comments.

Retail Exemption

Comment: Several commenters, including firms that prepare kit products and trade associations representing the meat and retail food industries, requested that FSIS revise the guideline to provide clarifying or additional information about eligibility for the retail exemption from FSIS inspection. One firm requested explanation of how the retail exemption applies to kits assembled and sold by retail grocery stores, prepared kits sold at retail, and kits sold through online marketplaces and other direct-to-consumer platforms. Several trade associations requested that FSIS clarify which meat or poultry components produced under the retail exemption need not bear all required features for labeling. One firm stated that such clarification would avoid manufacturer confusion about whether meal kits that include a recipe card would be eligible for the

retail exemption.

Response: The guideline does not apply to facilities preparing kits under the retail exemption from FSIS inspection (9 CFR 303.1(d) and 381.10(a)(1)) because these facilities were not previously required to assemble kits under FSIS inspection. The retail exemption remains unchanged by the guideline. Kits prepared under the retail exemption may only be sold directly to the end consumer and cannot be sold for resale. FSIS has updated the guideline to clarify that the scope of the document does not include products produced under the retail exemption. The original version and updated version of the guideline explain that FSIS labeling regulations, other than the requirement of the official inspection legend, apply to kits that are assembled under the retail exemption (9 CFR 303.1(f), 381.10(d)(4)).

Bulk Labeling

Comment: One firm that prepares kits requested clarification on whether FSIS inspection and label approval requirements apply to firms that receive and further process bulk product as part of final kit assembly, including portioning and packaging the meat component. Another firm that prepares kits using bulk-packed FSIS-inspected products asked whether the firm may make copies of the label on the bulk container and apply them to the product components that have been separated and rewrapped.

Response: FSIS has updated the guideline to clarify that

Agency guidance on the preparation of kit products without FSIS inspection does not apply when the meat or poultry component is processed, including portioned or packaged, by the firm assembling the kit. Such processing activities would require FSIS inspection if the production does not qualify for the retail exemption. Further, the resulting assembled kit product would require label approval by FSIS if the outer kit label met any of the conditions for required label approval under the regulations at 9 CFR 412.1. A firm portioning and repackaging bulk-packed products typically would not be permitted to make a copy of the original label since that label would likely bear the original establishment's USDA legend, company name, and a net weight.

Component Standard of Identity

Comment: One consumer requested clarification on whether, if the finished product of the meat or poultry component of a kit is labeled as a product that has a standard of identity, must the fully assembled kit label meet that standardized product name.

Response: FSIS updated the guideline to clarify that if a kit is labeled as a product with a standard of identity as defined under the regulations in 9 CFR part 319 or 381 subpart P, the components, once assembled, must meet the applicable standard of identity. For example, a "Beef Chili Kit" must contain 40 percent beef computed based on the weight of the fresh meat as described in 9 CFR 319.300.

Shipping Container Labeling

Comment: A USDA employee asked whether a shipping container comprising one or multiple kit products that were assembled at an official establishment without FSIS inspection would need to bear a USDA legend.

Response: The regulatory requirement that the shipping container bear a USDA legend (9 CFR 316.13 and 381.27) only applies to products that have been inspected and passed. FSIS updated the guideline to clarify that when a kit is assembled in an official establishment without FSIS inspection, the shipping container into which the kit is placed may not bear a USDA legend. In such case, the mark of inspection will be displayed on the label and packaging of the meat or poultry component included in the kit.

Outer Package Labeling

Comment: Comments from several trade associations, firms that prepare kit products, individuals, and one USDA employee asked FSIS to clarify what language should be used on the kit label to describe the product as a single unit of individual components. These commenters also asked where the description of the individual components should be displayed on the outer label.

Response: FSIS has updated the guideline to clarify that the requirements for the language on the outer kit label that identify the product as a kit are flexible. The outer label for the kit should identify all the individual components in the

kit, as well as identify the product as a single unit. The use of the word "kit" on the outer label is not required, nor is a specific location on the outer label for the identification of the individual components. For example, the outer label could display the product name "Chicken Barbecue Dinner Kit" or "Beef Lasagna Meal."

Immediate Package Labeling

Comment: One consumer asked whether FSIS would require safe handling instructions on the immediate package of a not ready to eat (NRTE) meat or poultry component in a kit.

Response: As stated in the guideline, if the meat or poultry component of a kit product is NRTE, the immediate package must include safe handling instructions in order to meet the regulatory requirements for kit assembly without FSIS inspection.

Export Labeling

Comment: One firm that exports kit products to Canada asked which package components need to include bilingual labels.

Response: FSIS does not require bilingual labels; however, Canada does have such labeling requirements (i.e., French and English). More information about Canada's requirements can be found on the Import and Export Library available at: <https://www.fsis.usda.gov/inspection/import-export/import-export-library>. FSIS inspectors verify and certify that products intended to be exported to a foreign country meet the foreign country's requirements.

Labeling Claims and Declarations

Comment: An animal welfare organization requested that FSIS require pre-market label approval for animal-raising claims on the exterior packaging of kit products.

Response: As a kit meeting the criteria as described in the guideline may be assembled without FSIS inspection and, as such, the outer label does not bear a USDA legend, the outer label is not subject to label approval requirements under the regulations at 9 CFR 412.1. Outer kit labels for products assembled without FSIS inspection under the conditions described in the guideline are required to comply with FSIS labeling requirements.

Comment: One firm that prepares kits requested that FSIS require allergen declarations to be displayed on the outer packaging and to prohibit ingredient statements on the meat or poultry component. The commenter stated that such requirements would reduce consumer confusion by identifying all allergens and other ingredients in a central location on the retail package.

Response: If the only component within the kit that includes an ingredients statement is the meat or poultry component, that should not cause any confusion. FSIS does not think that consumers will assume other unlabeled components, such as soy sauce or pasta, do not contain allergens. Both the outer kit label and the meat or poultry component must be fully labeled in compliance with FSIS labeling regulations. Therefore, the outer kit label will bear a complete ingredients statement that declares all ingredients in each component within

the kit. These labeling requirements were already explained in the previous version of the guideline; therefore, FSIS did not make any changes in response to this comment.

Comment: One individual asked FSIS to explain how the nutrition facts declaration should be displayed on a kit.

Response: A kit label bearing nutrition facts may present this information 1. centrally, based on the prepared, assembled product; 2. with separate panels for each component as packaged; or 3. as one panel with multiple columns for each component as packaged. The nutrition labeling requirements of 9 CFR 317.309 and 381.409 remain unchanged by this guideline. FSIS did not make any changes to the guideline based on this comment. Based on FSIS communications with these facilities, they understand nutrition labeling requirements.

Labeling Verification

Comment: One firm that prepares kits stated that the Agency should provide clear communication to FSIS inspectors to ensure the consistent application of kit labeling policies.

Response: FSIS will issue a directive to provide instructions to inspection program personnel for conducting verification activities for kit products to ensure compliance with FSIS regulations.

Mandatory and Voluntary FSIS Inspection

Comment: An FSIS employee requested that FSIS clarify whether a kit may be assembled under voluntary FSIS inspection and, therefore, bear a USDA inspection legend.

Response: FSIS clarified in the guideline that the assembly of a kit product as described in this guideline is eligible for voluntary inspection as a food inspection service under 9 CFR 350.3(c). FSIS also announced that, going forward, it will no longer conduct mandatory inspection services for such kits, as the Agency determined that providing inspection for these products as a voluntary food inspection service is the best use of Agency resources. After publication of this notice, FSIS will provide instructions for firms currently receiving mandatory inspection for such products regarding the procedures and timelines for withdrawing mandatory inspection and the option to seek voluntary inspection.

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this

Federal Register publication online through the FSIS Web page located at: <https://www.fsis.usda.gov/federal-register>. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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